MAR 3 - 2005

SECTION 11 SUMMARY OF SAFETY AND EFFECTIVENESS

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared:

a. Applicant:
OptiMedica Corporation
1793 Lafayette Street
Suite 105
Santa Clara, Ca. 95051

b. Contact Person:
Judy F. Gordon, D.V.M.
ClinReg Consulting Services, Inc.

Judy Gordon

c. Date Summary Prepared:
December 10, 2004

2. Name of device, including trade name and classification name:

Trade/Proprietary Name: Pascal™ Photocoagulator

Classification:
GEX
21 CFR 878.4810
Laser instrument, surgical, powered

HQF
21 CFR 886.4390
Laser, ophthalmic

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

510(k)	Company	Device Name
K022181	Lumenis, Inc.	Lumenis Novus Varia
K972514	Laserex Systems	Laserex LP1 532
K020374	Iridex Corporation	Iridex Oculight SL/SLx
K960971	Iridex Corporation	Iridex Medical Oculight GL
K971950	Infinitech, Inc.	Infinitech Slit Lamp Laser Adapter

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4. A description of the device that is the subject of the 510(k):

The Pascal laser photocoagulator is an integrated system comprising solid state aiming and treatment lasers, control electronics, graphical user interface, slit-lamp, and table. It is intended for use in the treatment of ocular pathology.

5. Statement of intended use:

The Pascal Photocoagulator indications for use are the following:

Intended for use in the treatment of ocular pathology in both the posterior and anterior segments.

Retinal photocoagulation, panretinal photocoagulation, focal photocoagulation and grid photocoagulation for vascular and structural abnormalities of the retina and choroid including:

- proliferative and nonproliferative diabetic retinopathy
- macular edema
- choroidal neovascularization
- branch and central retinal vein occlusion
- age-related macular degeneration
- lattice degeneration
- retinal tears and detachments
- Iridotomy, iridectomy and trabeculoplasty in angle closure and open angle glaucoma.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

The Pascal™ Retinal Photocoagulator system shares the same intended use, indications for use and the same or similar technological characteristics (including treatment wavelengths, laser active medium, pumping system, aiming beam, mode of operation, exposure duration, power, treatment intervals, spot size, semi-automatic repeat mode, controls and displays, laser energy delivery control (foot switch), and slit lamp delivery, and therefore is substantially equivalent to the predicate devices referenced in Item 3.

7. Brief summary of nonclinical tests and results:

Performance test results, as well as system and software hazard analysis information and system and software verification and validation information, have been submitted in conjunction with this Premarket Notification submission. The determination of substantial equivalence was based on the comparison of the technical characteristics between the Pascal Retinal Photocoagulator and the predicate laser systems.

8. Conclusion

The Pascal Retinal Photocoagulator is substantially equivalent to similar predicate laser devices and slit lamp delivery systems. The Pascal Retinal Photocoagulator shares the same intended use, indications for use, and technological characteristics as the predicate ophthalmic laser systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 - 2005

OptiMedica Corporation
c/o Judy F. Gordon, D.V.M.
ClinReg Consulting Services, Inc.
2 Delphinus
Irvine, California 92612

Re: K043486
Trade/Device Name: Pascal™ Photocoagulator
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 14, 2004
Received: December 17, 2004

Dear Dr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K043486

Device Name: Pascal™ Photocoagulator

Indications for Use:

The Pascal Photocoagulator indications for use are the following:

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Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043486

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Perscription Use X OR Over-The-Counter Use ____
(Optional Format 1-2-96)